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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,514	07/27/2001	Philippe Peltie	034299-337	7058

7590 10/07/2002

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EXAMINER	
LAVARIAS, ARNEL C	
ART UNIT	PAPER NUMBER
2872	

DATE MAILED: 10/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/915,514	Applicant(s) PELTIE ET AL.	
	Examiner Arnel C. Lavarias	Art Unit 2872	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2001 and 27 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 601.01(a). Specifically, the filing date of the listed application number is improperly identified.

Specification

2. The abstract of the disclosure is objected to because of the following informalities:

All instances of reference numerals to figures should be removed.

Abstract, line 11- delete 'Fig. 1.'.

Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities:

Page 1, line 23- "Nuclei" should read "Nucleic"

Page 2, line 2- "DANA" should read ""DNA"

Page 2, line 21- "provides" should read "provided"

Page 3, lines 5-9- The intended meaning of this paragraph is unclear and ambiguous.

Page 3, line 20- "of" should read "for"

Page 7, line 5- insert "8" after "camera"

Page 7, line 24- "4" should read "four"

Appropriate correction is required.

Claim Objections

4. The claims are objected to because they include reference characters which are not enclosed within parentheses.

Reference characters corresponding to *elements recited in the detailed description of the drawings* and used in conjunction with the recitation of the same element or group of elements in the claims should be enclosed within parentheses so as to avoid confusion with other numbers or characters which may appear in the claims. See MPEP § 608.01(m).

5. Claims 1-15 are objected to because of the following informalities:

Claims 1-3 recite the limitation "the microchannels" in line 10 of Claim 1, and line 2 of Claims 2 and 3. There is insufficient antecedent basis for this limitation in the claim. Claims 4-14 are dependent, directly or indirectly, on Claims 1 or 3, and therefore inherit the deficiencies of Claims 1-3.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-2, 4-5, 8, 9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoyt (US2001/0046050) or Hoyt (US20010033374) in view of Kopf-Sill et al.

With regard to Claims 1-2, 4, 8, and 12, Hoyt (US2001/0046050) and Hoyt (US20010033374) both disclose a fluorescence image device comprising first means for containing constituents to be analyzed (See for example 13 in Figure 1 of Hoyt (US2001/0046050)), second means for illuminating with polarized light the constituents to be analyzed (See for example 10 in Figure 1 of Hoyt (US2001/0046050)) and third means for reading out a fluorescence light emitted by the constituents under the action of the polarized light (See for example 18 in Figure 1 of Hoyt (US2001/0046050)), characterized in that the second means comprise at least one coupling device, such as a diffraction grating, for guiding polarized light into the first means for containing the constituents (See for example 5 in Figure 1 of Hoyt (US2001/0046050); paragraph 0043). Hoyt (US2001/0046050) or Hoyt (US20010033374) additionally disclose the second means comprising a laser (See for example 10 in Figure 1 of Hoyt (US2001/0046050)) and the third means comprising a birefringent crystal (See for example 20 in Figures 1 or 2 of Hoyt (2001/0046050)), such as calcite (See for example paragraphs 0045, 0049 in Hoyt (2001/0046050)). Hoyt (US2001/0046050) and Hoyt (US20010033374) both lack the first means for containing constituents to be analyzed consisting of a parallel microchannel structure. However, Kopf-Sill et al. teaches a high throughput analytical apparatus for performing fluorescence detection wherein the means for containing the

constituents is a parallel microchannel plate (See Figures 1 and 13), which is characterized in that the microchannels are etched in a transparent material, such as glass (See col. 7, lines 2-11). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a parallel microchannel plate as taught by Kopf-Sill et al. in the fluorescence imaging device as disclosed by Hoyt (US2001/0046050) or Hoyt (US20010033374). One would have been motivated to do this to take advantage of microfluidic analytical techniques, such as small sample volumes and low cost ease of fabrication of the microfluidic substrate.

With regard to Claim 5, Hoyt (US2001/0046050) or Hoyt (US20010033374) discloses the invention as set forth above. Hoyt (US2001/0046050) or Hoyt (US20010033374) lacks the coupling device comprising a cylindrical lens. However, Kopf-Sill et al. teaches a high throughput analytical apparatus for performing fluorescence detection wherein the coupling device comprises a cylindrical lens (See 614 in Figure 13; col. 16, line 46-col. 17, line 25). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a cylindrical lens as the coupling device, as taught by Kopf-Sill et al., in the fluorescence imaging device as disclosed by Hoyt (US2001/0046050) or Hoyt (US20010033374). One would have been motivated to do this to provide excitation light to a longer surface area of the microfluidic substrate.

With respect to Claims 9 and 11, Hoyt (US2001/0046050) or Hoyt (US20010033374) discloses the invention as set forth above. Hoyt (US2001/0046050) or Hoyt (US20010033374) lacks the laser emitting substantially between 488-514 nm or 550-580

nm. However, Kopf-Sill et al. teaches a high throughput analytical apparatus for performing fluorescence detection wherein the laser is capable of emitting in a wavelength range between 330-700 nm (See col. 18, lines 19-36). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the laser emit at substantially between 488-514 nm or 550-580 nm, as taught by Kopf-Sill et al., in the fluorescence image device as disclosed by Hoyt (US2001/0046050) or Hoyt (US20010033374). One would have been motivated to do this to provide appropriate excitation wavelengths depending on the fluorescent tags selected for the sample constituents.

8. Claims 3, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoyt (US2001/0046050) or Hoyt (US20010033374) in view of Kopf-Sill et al. as applied to Claim 1 above, and further in view of Nordman et al.

Hoyt (US2001/0046050) or Hoyt (US20010033374) in view of Kopf-Sill et al. discloses the invention as set forth above in Claim 1. Hoyt (US2001/0046050) or Hoyt (US20010033374) in view of Kopf-Sill et al. lacks the microchannels being flexible capillaries. However, Nordman et al. teaches a multichannel capillary electrophoresis device for use in fluorescence detection wherein the constituents flow through flexible capillaries (See for example Figures 1 or 2; col. 3, line 62-col. 4, line 57). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate flexible capillaries, as taught by Nordman et al., in the fluorescence image device as disclosed by Hoyt (US2001/0046050) or Hoyt (US20010033374) in view of Kopf-Sill et al. One would have been motivated to do this

to provide high-pressure fluid flow for sample movement along the microfluidic substrate.

9. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoyt (US2001/0046050) or Hoyt (US20010033374) in view of Kopf-Sill et al. as applied to Claim 1 above, and further in view of Stabile et al. and Stabile et al.

Hoyt (US2001/0046050) or Hoyt (US20010033374) discloses the invention as set forth above in Claim 1. Hoyt (US2001/0046050) or Hoyt (US20010033374) lacks the third means comprising a first polarizing filter and a second polarizing filter. However, Modlin et al. teaches an apparatus for performing fluorescence polarization measurements wherein the third means for reading out a fluorescence light (See for example 144 in Figure 8) comprises a first polarizing filter (See P filter of 132 in Figure 8) and a second filter (See S filter of 132 in Figure 8). Additionally, Stabile et al. teaches an apparatus for detecting polarized fluorescence light from a sample (See for example Figures 1B or 2), wherein the first and the second polarizing filters are located on a filter wheel (See for example 4B in Figure 2; col. 10, lines 14-34). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a first and a second polarizing filter in a filter wheel as part of the means for reading out the fluorescence light, as taught by Modlin et al. and Stabile et al., in the fluorescence image device as disclosed by Hoyt (US2001/0046050) or Hoyt (US20010033374) in view of Kopf-Sill et al. One would have been motivated to do this to eliminate polarized background signals from the fluorescence signal, thus increasing

the signal-to-noise ratio of the detection system, while allowing for automated selection of the polarizer.

10. Claims 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoyt (US2001/0046050) or Hoyt (US20010033374) in view of Kopf-Sill et al. as applied to Claim 1 above, and further in view of Modlin et al.

Hoyt (US2001/0046050) or Hoyt (US20010033374) in view of Kopf- Sill et al. discloses the invention as set forth above in Claim 1. Hoyt (US2001/0046050) or Hoyt (US20010033374) in view of Kopf- Sill et al. lacks a second microlaser for simultaneously illuminating a second area of the microchannel structure. However, Modlin et al. teaches an apparatus for performing fluorescence polarization measurements (See for example Figure 5) wherein a second laser (See103a-d in Figure 5) simultaneously illuminates a second area of the microchannel structure (See area near 120 in Figure 5). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a second laser to illuminate a second area of the microchannel, as taught by Modlin et al., in the fluorescence image device as disclosed by Hoyt (US2001/0046050) or Hoyt (US20010033374) in view of Kopf-Sill et al. One would have been motivated to do this to perform simultaneous top and bottom illumination with simultaneous top and bottom detection of fluorescence signals.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arnel C. Lavarias whose telephone number is 703-305-4007. The examiner can normally be reached on M-F 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cassandra Spyrou can be reached on 703-308-1687. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7722 for regular communications and 703-308-7722 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1782.

Arnel C. Lavarias
September 27, 2002

Cassandra Spyrou
Supervisory Patent Examiner
Technology Center 2800